UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF OKLAHOMA

JENNIFER HAYES and JUSTIN HAYES, Individually and as Next Friends of K.H., a minor,	)	
Plaintiffs,	)	
v.	)	**Case No. 07-CV-0682-CVE-SAJ**
SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE,	)	
Defendant.	)	

OPINION AND ORDER

Before the Court is the Plaintiffs' Motion and Memorandum for Leave to File Amended Complaint (Dkt. # 84). Plaintiffs request leave to amend the complaint to add an additional defendant, GlaxoSmithKline plc ("GSK plc").[1] Defendant SmithKline Beecham Corporation d/b/a GlaxoSmithKline ("SKB") argues that leave to amend should be denied because (1) the addition of GSK plc would be futile and (2) plaintiffs' motion is in bad faith. For the reasons stated below, plaintiffs' motion is denied.

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[1] In its reply brief (Dkt. # 146), plaintiffs seek to add a second additional defendant, GlaxoSmithKline Research and Development, Ltd. ("GSK R&D"), and attach a proposed second amended complaint. GSK R&D is the research arm of GSK plc and is responsible for product safety worldwide. Dkt. # 146, at 2. Pursuant to local rule, a party may not include a motion in a response brief. See N.D. LCvR 7.2(c)("A response to a motion may not also include a motion or cross-motion made by a responding party."); N.D. LCvR 7.2(h)("Reply briefs regarding a new matter in the response brief may be filed within fourteen (14) days after the due date of the response."). Although the request should not have been included in a reply brief, the Court will address the request in order to avoid an additional motion and briefing.

I.

Plaintiffs Jennifer and Justin Hayes filed this lawsuit individually and on behalf of K.H., a minor, alleging that Jennifer Hayes' use of the medication Paxil during pregnancy resulted in K.H.'s heart defects and related medical problems. Dkt. # 84. Defendant SKB is a U.S. subsidiary (through several layers of subsidiaries) of GSK plc, a United Kingdom ("UK") corporation. Id.; Dkt. # 117-2, at 2. According to defendant, GSK plc is a corporation with the sole purpose of holding subsidiary companies. Dkt. # 117-2, at 2. GSK plc does not engage in activities related to the "research, development, manufacture, marketing or sale of prescription drugs in the United States or elsewhere." Id. at 3.

Paxil, an anti-depressant, was first released in the United States in 1992. Dkt. # 84 at 8. In December 2006, the American College of Obstetricians and Gynecologists warned pregnant women to avoid taking Paxil because of an increased risk of birth defects. Id. at 11. Specifically, it was suggested that any woman who took Paxil early in her pregnancy have a fetal echocardiogram to determine whether any damage occurred to the fetus' heart. Id. at 11. Jennifer Hayes took Paxil from January 2005 until the end of March 2005. Id. at 9. She was pregnant with K.H. for some of that time. Id. K.H. was born on December 1, 2005 and was subsequently diagnosed with a heart defect. Id. at 6, 9. In the months that followed, K.H. had open-heart surgery and several other operations related to his heart defect. Id. at 9. At present, K.H. suffers from numerous medical problems and requires daily medications and treatments. Id. at 10.

Plaintiffs filed their complaint on November 29, 2007, asserting the following claims against SKB: (1) manufacturer's products liability;[2] (2) negligence and gross negligence; (3) deceptive trade practices; (4) breach of warranty; and (5) negligence per se. Since then, numerous discovery motions have been filed and the magistrate judge has ruled on various discovery disputes. Plaintiffs contend that defendant has failed to give them access to UK-based witnesses under defendant's control. Dkt. # 84, at 2. Defendant responds that it has made GSK employees available for depositions and has provided over one million pages of documents. Dkt. # 117. Pursuant to the Court's most recent scheduling order (Dkt. # 69), the discovery period will close on March 31, 2009. Plaintiffs now seek to add GSK plc and GSK R&D and assert the same claims against those entities.

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[2] The Court has reviewed plaintiffs' proposed amended and second amended complaints in their entirety and reminds plaintiffs of their duty of candor in all factual representations made to the Court. Pursuant to Federal Rule of Civil Procedure 11, an attorney certifies that the factual represenations contained in a pleading have "evidentiary support." Here, plaintiffs rely upon an FDA release to support their claim that Paxil was defectively manufactured. Dkt. # 84, at 12. However, this reference is misleading. The FDA seizure of Paxil on March 4, 2005 described in the release had no relation to plaintiffs' claim that Paxil caused K.H.'s birth defects. See U.S. Marshals Seize Lots of GlaxoSmithKline's Paxil CR and Avandamet Tablets Because of Continuing Good Manufacturing Practice Violations, FDA News, P05-10 (March 4, 2005), *available at* http://www.fda.gov/bbs/topics/news/2005/NEW01162.html. The seizure was made because some of the Paxil CR tablets produced at manufacturing facilities in Cidra, Puerto Rico and Knoxville, Tennessee could split apart and cause a patient to receive a portion of the tablet lacking any active ingredient. Id. The FDA was clear that the defect was not believed to be harmful to consumers, and instructed patients to continue taking their medication and consult with their physicians. Id. The seizure had no relation to the pregnancy warnings later issued for Paxil, and accordingly has no relation to plaintiffs' claim. Thus, plaintiffs' use of the FDA release as evidence that defendant's product was defectively manufactured is misleading in this case. This Court expects plaintiffs' counsel to verify the accuracy of all factual representations made.

II.

A motion to add a party by amending a complaint is governed by Rule 15 of the Federal Rules of Civil Procedure. Rule 15(a) provides that "leave [to amend] shall be freely given when justice so requires." Minter v. Prime Equipment Co., 451 F.3d 1196, 1204 (10th Cir. 2006); Bradley v. Val-Mejias, 379 F.3d 892, 900 (10th Cir. 2004). "In the absence of any apparent or declared reason-such as undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance ... the leave sought should, as the rules require, be 'freely given.'" Foman v. Davis, 371 U.S. 178, 182 (1962). Leave may also be denied if the amendment would be futile and subject to dismissal under Rule 12. Jefferson County Sch. Dist. No. R-1 v. Moody's Investor's Services, Inc., 175 F.3d 848, 859 (10th Cir. 1999). In sum, while leave to amend may be "freely given" in certain circumstances, the decision to grant such a motion lies squarely in the Court's discretion and is reviewed for abuse of that discretion on appeal. See Minter, 451 F. 3d at 1204 ("[T]he grant of leave to amend the pleadings pursuant to Rule 15(a) is within the discretion of the trial court and we will not reverse the court's decision absent an abuse of discretion.") (internal citations omitted).

III.

Defendant challenges plaintiffs' proposed amended complaint (and presumably the second amended complaint) on the grounds of bad faith and futility, arguing that it would be futile to add GSK plc (and presumably GSK R&D)[3] because plaintiffs cannot state a claim as to those entities

[3] Plaintiffs did not seek to add GSK R&D in their motion to amend the complaint (Dkt. # 84). Accordingly, defendant did not have the opportunity in its response brief to address this request. See note 1, supra.

upon which relief may be granted. "Where a complaint, as amended, would be subject to dismissal, leave to amend need not be granted." Mountain View Pharmacy v. Abbott Lab., 630 F.2d 1383, 1389 (10th Cir. 1980). See also Ketchum v. Cruz, 961 F. 2d 916, 920 (10th Cir. 1992) (citing Foman, 371 U.S. at 182). Plaintiffs' proposed amended and second amended complaints assert the following five claims: (1) manufacturer's product liability; (2) negligence and gross negligence; (3) deceptive trade practices; (4) breach of warranty; and (5) negligence per se. Each will be addressed in turn.

A. Manufacturer's Strict Products Liability

Under Oklahoma law, a plaintiff must prove three elements to recover on the theory of manufacturer's strict products liability: "(1) the product was the cause of the injury; (2) the defect existed in the product at the time it left the manufacturer's possession and control; and (3) the defect made the product unreasonably dangerous to the plaintiff or his property." Kirkland v. General Motors Corp., 521 P.2d 1353, 1363 (Okla. 1974). "The alleged defect may be the result of a problem in the product's design or manufacture, or it may be the result of inadequate warnings regarding use of the product." Wheeler v. HO Sports Inc., 232 F.3d 754, 757 (10th Cir. 2000) (quotation omitted). A "manufacturer" for liability purposes includes "processors, assemblers, and all other persons who are similarly situated in processing and distribution." Kirkland, 521 P. 2d at 1361.

It is clear from the record and from defendant's own admission (Dkt. # 6, at 2) that SKB is the manufacturer of Paxil in the United States. It is also clear from the definition of "manufacturer" that GSK plc and GSK R&D did not manufacture, process, or assemble Paxil in the United States. Instead, it appears from the record that GSK plc is the ultimate parent company of GSK and, while it might profit from the manufacture and sale of Paxil in the United States, GSK plc is not engaged

in manufacturing, processing or assembling Paxil for sale in Oklahoma. Similarly, GSK R&D monitors the safety of Paxil worldwide, but does not produce or sell it. Thus, even if plaintiffs were permitted to amend the complaint to add GSK plc and GSK R&D as defendants, such claims would be subject to dismissal, making amendment futile.

B. Plaintiffs' Negligence Claims[4]

Plaintiffs also seek to assert claims that GSK plc and GSK R&D were negligent, grossly negligent, and/or negligent per se in the "testing, manufacturing, marketing, labeling, and promoting of Paxil." Dkt. # 84, at 13. Under Oklahoma law, the elements of common law negligence are: "(1) the existence of a duty on the part of the defendant to protect plaintiff from injury; (2) a violation of that duty; and (3) injury proximately resulting therefrom." Sloan v. Owen, 579 P.2d 812, 814 (Okla. 1977). "The existence of a duty is an essential element of a negligence claim; without it the claim must fail." Henry v. Merck and Co., Inc., 877 F.2d 1489, 1492 (10th Cir. 1989). Under Oklahoma law, the manufacturer and each member in the chain of distribution of a product owes a duty of reasonable care. See Barnhart v. Freeman Equipment Co., 441 P. 2d 993 (Okla. 1968); Crane Co. v. Sears, 35 P. 2d 916 (Okla. 1934); As stated above, GSK plc and GSK R&D did not manufacture or distribute Paxil in the United States. Thus, GSK plc and GSK R&D did not breach a duty to plaintiffs and cannot be liable on a negligence theory. Accordingly, amending the complaint to include negligence claims against GSK plc and GSK R&D would be futile.

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[4] Plaintiffs assert negligence claims on the theories of negligence, gross negligence, and negligence per se; for the purposes of this motion, all of plaintiffs' negligence-based claims will be addressed generally.

C. Deceptive Trade Practices

Plaintiffs' attempt to assert claims against GSK plc and GSK R&D for violations of Oklahoma's Consumer Protection Act ("OCPA") would also be futile. Under the OCPA, a person engages in an unlawful practice when, in the course of the person's business, the person makes a false representation, or commits an unfair or deceptive trade practice. See OKLA. STAT. tit. 15, § 753 (5, 20). Plaintiffs assert that the "nondisclosure of the dangers inherent in the use of Paxil and subsequent sale to consumers" was "misleading" and a "misrepresent[ation]," and thus violates the OCPA. However, because GSK plc and GSK R&D do not do business in the United States, neither one has engaged in an unfair or deceptive practice in Oklahoma. Accordingly, an amendment to include deceptive trade practices claims against either entity would be futile.

D. Breach of Warranty

Under Oklahoma law, a seller of a product may be liable for a breach of warranty if, inter alia, "any affirmation of fact or promise made by the seller to the buyer which relates to the the goods and becomes part of the basis of the bargain." See OKLA. STAT. tit. 12, § 2-313. Here, plaintiffs move to amend the complaint to assert a claim of breach of warranty against GSK plc and GSK R&D. Because neither GSK plc or GSK R&D are "sellers" under the meaning of the statute, such an amendment would be futile. See OKLA. STAT. tit. 12, § 2-103. ("'Seller' means a person who sells or contracts to sell goods."). Plaintiffs cannot state a claim for breach of warranty against GSK plc or GSK R&D upon which relief may be granted. Thus, it would be futile to amend the complaint to add this claim against GSK plc and GSK R&D.

IV.

Defendant's futility argument notwithstanding, there is sufficient cause to deny plaintiffs' motion to amend the complaint. First, defendant argues that plaintiffs' motion to amend is in bad faith because plaintiffs move to amend for an improper purpose. In their motion, plaintiffs explicitly state that they move to amend the complaint to add GSK plc (and presumably GSK R&D) "for the purpose of securing needed testimony from fact witnesses." Dkt. # 84. Plaintiffs also state that this motion "was the result of many months of Defendant's refusal to cooperate in discovery of this case." Dkt. # 146. Defendant alleges that plaintiffs' attempt to add GSK plc (and presumably GSK R&D) is merely an attempt to circumvent the discovery process and gain access to certain witnesses without complying with procedures set forth in the Hague Convention for depositions in foreign countries. It would be an abuse of discretion to amend the complaint to facilitate discovery when plaintiffs cannot state a claim against these defendants. Plaintiffs will not be permitted to add parties for the purpose of gaining easier access to GSK plc and GSK R&D employees in the absence of any valid claims against either entity.

Finally, plaintiffs have failed to articulate a reason why they should be permitted to add additional defendants at this stage of the litigation. Plaintiffs were certainly aware at the time this suit was filed that SKB was the U.S. subsidiary of GSK plc. If plaintiffs had a valid claims against SKB's parent company, they should have been stated in the complaint. This case was filed one year ago and the parties are currently four months away from the close of discovery. There is no evidence in the record to suggest that plaintiff has learned of any fraud, asset transfers, or lack of corporate separateness to cause SKB to be unable to satisfy a judgment. Accordingly, there is no reason to add SKB's parent company. At this late date, adding additional defendants would likely cause delay and

would force defendant to incur additional expenses. The Court finds that plaintiffs' motive for filing this motion, while not necessarily in bad faith, is dilatory. Accordingly, plaintiffs should not be permitted to amend their complaint to add GSK plc and GSK R&D as additional defendants.

IT IS THEREFORE ORDERED that Plaintiffs' Motion and Memorandum for Leave to File Amended Complaint (Dkt. # 84), as well as the request in the reply brief (Dkt. # 146) to file the proposed second amended complaint, are **denied**.

DATED this 20th day of November, 2008.

Claire V Eagan

CLAIRE V. EAGAN, CHIEF JUDGE
UNITED STATES DISTRICT COURT